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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/828,395

04/19/2004

John K. Jackson

UBC.P-032

5836

57381

7590

05/25/2006

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EXAMINER

VIVLEMORE, TRACY ANN

ART UNIT

PAPER NUMBER

1635

DATE MAILED: 05/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/828,395

Applicant(s)

JACKSON ET AL.

Examiner

Tracy Vivlemore

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 4,5,9,10,14 and 15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,6-8 and 11-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Any rejection not reiterated in this Action is withdrawn.

Claim Objections

Claim 11 is objected to because of the following informalities: the word non-cancerous is misspelled in line 2. Appropriate correction is required.

Response to arguments: Claim Rejections - 35 USC § 112

Claims 1 and 6 remain rejected and new claim 11 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons set forth in the office action mailed on December 27, 2005.

Applicant asserts that the examiner is requiring applicant to test and discover every conceivable method for performing the methods of the invention. Applicant further asserts the examiner "says that the claims must be limited to the genus of the specific examples" and that applicants are aware of no such burden imposed by the law of the United States. The rejection of record does not make any such requirements. The instant claims do not satisfy the written description requirement because the description of antisense oligonucleotides and siRNAs targeted to human clusterin provided by the specification does not describe the full genus of nucleic acid and non-nucleic acid inhibitors that are encompassed by the claims. The structure of an antisense oligonucleotide does not lead the skilled artisan to the structure of any other type of inhibitor that has the function of inhibiting clusterin in all species. Applicant's

arguments do not address the relationship of the structure of the disclosed inhibitors and the claimed function of inhibiting clusterin for the purpose of treating disease and thus do not overcome the rejection of record.

Claims 1-3 and 6-8 remain rejected and new claims 11-13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for reduction of clusterin expression by administration of an antisense oligonucleotide targeted to clusterin in cells *in vitro*, does not reasonably provide enablement for treatment of a non-cancerous angiogenesis-related disease by administration of an antisense oligonucleotide targeted to clusterin in any organism for the reasons of record set forth in the office action mailed December 27, 2005.

In response to the scope of enablement rejection applicant has submitted a declaration submitted in another application in response to an enablement rejection. This declaration is not sufficient to overcome the instant rejection because it describes delivery and treatment of cancerous conditions while the instant claims are directed to treatment of conditions that specifically exclude cancer. Therefore, the declaration does not provide evidence of delivery and treatment of disease that is commensurate in scope with the instant claims.

Response to arguments: Claim Rejections - 35 USC § 102

Claims 6 and 7 remain rejected and claims 1, 2, 11 and 12 are rejected under 35 U.S.C. 102(b) as anticipated by Monia et al. for the reasons of record set forth in the office action mailed December 27, 2005.

Applicant argues that claim 6 is directed to treatment of "cells associated with a non-cancerous angiogenesis-related disease", a limitation that is not addressed by the art rejections. Because the claim previously recited treating cancer cells, this amendment is sufficient to overcome the art rejections over each of the Gleave et al. references but does not overcome the rejection over Monia et al.

While Monia et al. is silent with regard to inhibition of clusterin resulting in reduction of angiogenesis, Monia et al. disclose at column 3, lines 40-46 a method of treating an animal having a disease associated with expression of clusterin using an antisense oligonucleotide. Performing this method would be a treatment of cells associated with a disease. At column 2, line 65 through column 3, line 6 Monia et al. disclose that overexpression of clusterin is associated with atherosclerosis, a disease disclosed in the instant specification as being a non-cancerous angiogenesis-related disease. Thus, Monia et al. disclose a method of inhibiting clusterin expression in disease-associated cells and individuals suffering from such diseases that absent evidence to the contrary would reduce angiogenesis and treat a non-cancerous angiogenesis-related disease.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tracy Vivlemore whose telephone number is 571-272-2914. The examiner can normally be reached on Mon-Fri 8:45-5:15.

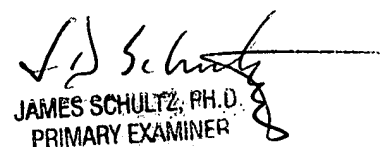
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 571-272-4517. The central FAX Number is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Tracy Vivlemore
Examiner
Art Unit 1635

TV
May 16, 2006


JAMES SCHULTZ, PH.D.
PRIMARY EXAMINER